REMARKS

Claims 28-42 are pending in the application following entry of the foregoing amendment. Claims 1-27 are canceled, without prejudice to the applicant refilling claims of the same or similar scope in later applications.

The applicants respectfully traverse the rejections under 35 USC §§ 102(b) and 103(a) and request reconsideration in view of the foregoing new claims.

While the previously pending claims were subject to the §§ 102(b), 103(a) rejections are now canceled, and hence the rejection rendered moot, the applicants believe it helpful to place the Yamamoto et al. reference in context and distinguish new claims 28-48.

Yamamoto et al. address issues associated with and the need for anticoagulation therapy during hemodialysis, and in particular, the resulting complication of heparin induced thrombocytopenia. Blood circulating in the hemodialysis device tends to form clots due to the absence of the natural protective shield of the patient's vascular system and to the exposure to of the blood to the negatively charged surfaces of the hemodialysis circuitry. To prevent clot formation, "... anticoagulation by heparin is the standard method in hemodialysis." (Yamamoto et al., Column 2, lines 4-5).

In order to prevent clot formation during hemodialysis, a fixed dose of heparin is given to all hemodialysis patients, regardless of their individual hemostasis conditions. As a result, some patients are under-anticoagulated, resulting in clot formation; others are over-anticoagulated, resulting in bleeding. Therefore, clot formation in the hemodialysis circuitry is neither unique nor specific to HiT patients only. This is the reason Yamamoto et al. suggest that, when using their test, one should measure platelet number and run aggregometry and ELISA tests to confirm.

In accordance with a HiT determination procedure and associated apparatus in accordance with preferred embodiments of the present invention, an excessive concentration of heparin – far more than would be given to a patient – is used to prevent any possible clot formation. As a result, the only way a clot forms is when Factor 4 (PF4) combines with heparin and heparin-induced antibodies from the HiT patient.

In the inventive test for HiT, it is believed that there is no other way for that clot to form, except in the presence of the patient's HiT antibodies. Thus, the method and associated apparatus are novel and patentable in their ability to assess the presence of HiT antibodies, e.g., the PF4-heparin-HiT antibody complex. In particular, Yamamoto et al. speak nothing to the idea of using an overwhelming dosage of heparin in a testing methodology to identify clot formation resulting from the presence of heparin-induced antibodies.

To establish a *prima facie* case of obviousness, the cited references alone or in combination must teach each and every limitation of the claims. Failing to teach each and every limitation of the claim, the proffered combination fails to render the claimed combination unpatentable. It is because, for the reasons set forth above, that the proffered combination including Yamamoto et al. fails to teach each and every limitation of the claims that the pending claims are allowable, and such action is requested.

Moreover, each of the claims set forth testing a whole blood sample to determine whole blood characteristics. Yamamoto et al. speak only to measuring platelet number, platelet aggregometry and ELISA testing to confirm platelet number and their ability to participate in the clotting process. Hemostasis is a complex process of which platelets and platelet function are a part. Testing only platelet number and platelet aggregation does not yield blood sample characteristics useful to determining HiT in accordance with embodiments of the claimed invention. For example, testing only platelet number and their ability to aggregate will not provide information as to other complexes involved in the hemostasis process, and particularly those complexes indicative of HiT. Thus, Yamamoto et al. fail to teach or suggest testing whole blood samples to determine blood sample characteristics, and is not capable of providing the result provided by embodiments of the claimed invention.

Thus, the applicant submits claims 28-42 are allowable, and such action is requested. Moreover, in view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: April 28, 2008

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